REMARKS

This Amendment & Response amends claims 1 and 2, cancels no claims, and adds no new claims. Claims 1-4 remain pending in the application.

Objections/Rejections
Under 35 U.S.C. §112

1.0 *The Examiner has rejected claims 1 and 2 under 35 U.S.C. §112, second paragraph for lack of clarity as to whether the "hermetically sealed packaging" is a component of the claimed invention or a statement of intended use.*

Applicant has amended claims 1 and 2 to clarify that a hermetically sealed package is NOT a component of the claimed invention.

Withdrawal of this rejection is respectfully requested.

Double Patenting Rejections

2.0 *The Examiner has rejected claim 1 on the grounds of nonstatutory obviousness-type double patenting over commonly owned US Patent 7,252,014.*

A Terminal Disclaimer as to commonly owned US Patent 7,252,014 is attached.

Withdrawal of this rejection is respectfully requested.

3.0 *The Examiner has provisionally rejected claim 1 on the grounds of nonstatutory obviousness-type double patenting over commonly owned US pending patent application 11/453,321.*

A Terminal Disclaimer as to commonly owned US pending patent application 11/453,321 is attached.

Withdrawal of this rejection is respectfully requested.

4.0 *The Examiner has rejected claim 2 on the grounds of nonstatutory obviousness-type double patenting over commonly owned US Patent 7,252,014 in view of US Patent 5,212,993.*

A nonstatutory double patenting rejection is a judicially created rejection used to prevent prolongation of patent coverage for an invention by prohibiting the granting of claims in a patent application that are not patentably distinguishable from claims in another patent or patent application. A double patenting rejection assesses the patentability of claims in a patent application over claims in another patent or patent application without reference to extraneous prior art. It is improper to combine patents and/or patent applications to establish a nonstatutory double patenting rejection. *See*, M.P.E.P. §804 et seq. Hence, the Examiner's combination of US Patents 7,252,014 and 5,212,993 in an effort to establish a nonstatutory double patenting rejection is improper and must be withdrawn.

5.0 *The Examiner has rejected claim 2 on the grounds of nonstatutory obviousness-type double patenting over commonly owned US pending patent application 11/453,321 in view of US Patent 5,212,993.*

As set forth above in section 4.0, a nonstatutory double patenting rejection is a judicially created rejection used to prevent prolongation of patent coverage for an invention by prohibiting the granting of claims in a patent application that are not patentably distinguishable from claims in another patent or patent application. A double patenting rejection assesses the patentability of claims in a patent application over claims in another patent or patent application without reference to extraneous prior art. It is improper to combine patents and/or patent applications to establish a nonstatutory double patenting rejection. See, M.P.E.P. §804 et seq. Hence, the Examiner's combination of US pending patent application 11/453,321 and 5,212,993 in an effort to establish a nonstatutory double patenting rejection is improper and must be withdrawn.

Objections/Rejections
Under 35 U.S.C. §103

6.0 *The Examiner has rejected claims 1-4 as obvious under 35 U.S.C. §103(a) over Mayer (United States Patent 5,212,993) in view of Gürich et al. (United States Patent 5,203,822).*

SUMMARY OF CITED REFERENCES

Mayer discloses an instrument and method for measuring the concentration of oxygen in a hermetically sealed package (40). The instrument includes (a) a needle (12) having a lumen, (b) an oxygen sensor (18), and (c) a vacuum pump (30) for pulling a gas sample from a hermetically sealed package through the lumen in the needle and into the oxygen sensor.

Gürich et al. discloses an instrument and method for measuring the compression volume in a cylinder of an internal combustion engine. One of the steps in the method involves introducing gas into the cylinder at different known flow rates to produce an overpressure within the cylinder until a steady state pressure is observed within the cylinder at each flow rate (*i.e.*, flow rate in equals flow rate out through leaks in the cylinder). The steady state pressure achieved within the cylinder at each known flow rate is measured and recorded. A leakage characteristic Q(p) can be calculated from these values, for later use along with other measured and calculated values to determine the compression volume of the cylinder. Gürich et al. discloses that the flow rate can be determined by employing a gas flow controller (3) or optionally a mass flow rate sensor. *See*, Column 5, Lines 24-30 of Gürich et al.

SUMMARY OF CLAIMED INVENTION

A **First Aspect of the Invention** (claim 1) is an instrument for detecting leaks in hermetically sealed packaging. The instrument includes (a) a needle having a lumen, (b) a mass flow rate sensor, and (c) a vacuum pump. The mass flow rate sensor is in sealed fluid communication with the lumen defined by the needle. The vacuum pump is in fluid communication with both the lumen defined by the needle and the mass flow rate sensor. The instrument is effective for evacuating gas from a hermetically sealed package through the lumen in the needle and directing mass flow from the evacuated package into operable contact with the

mass flow rate sensor so as to permit sensing of any continuing mass flow from the package once the package has been evacuated.

A **Second Aspect of the Invention** (claim 2) is an instrument for analyzing oxygen concentration of a gas within hermetically sealed packaging and detecting leaks in hermetically sealed packaging. The instrument includes (a) a needle having a lumen, (b) an oxygen sensor, (c) a mass flow rate sensor, and (d) a vacuum pump. The oxygen sensor and the mass flow rate sensor are in sealed fluid communication with the lumen defined by the needle. The vacuum pump is in fluid communication with the lumen defined by the needle and both the oxygen sensor and the mass flow rate sensor. The instrument is effective for (A) pumping a sample of a gas from within a hermetically sealed packaging through the lumen of the needle and into operable contact with the oxygen sensor for permitting sensing of an oxygen concentration of the sample, (B) evacuating the gaseous content of the hermetically sealed packaging, and (C) directing mass flow from the evacuated packaging into operable contact with the mass flow rate sensor so as to permit sensing of any continuing mass flow from the evacuated packaging

A **Third Aspect of the Invention** (claim 3) is a method of detecting leaks in hermetically sealed packaging. The method involves (a) selecting a hermetically sealed packaging, (b) puncturing the hermetically sealed packaging with a hollow needle having a lumen, (c) evacuating any gaseous content from within the hermetically sealed packaging through the lumen of the needle to form a vacuum within the hermetically sealed packaging, and (d) measuring mass flow rate from within the evacuated hermetically sealed packaging. Sensing of a mass flow rate from the evacuated hermetically sealed packaging above a threshold value indicates a leak in the hermetically sealed packaging.

A **Fourth Aspect of the Invention** (claim 4) is a method of analyzing oxygen concentration of a gas within hermetically sealed packaging and detecting leaks in the hermetically sealed packaging. The method involves (a) selecting a hermetically sealed packaging, (b) puncturing the hermetically sealed packaging with a hollow needle having a lumen, (c) pumping a sample of the gas within the hermetically sealed packaging through the lumen of the needle and into operable contact with an oxygen sensor for sensing the oxygen

concentration in the sample, (d) evacuating the gaseous content from within the hermetically sealed packaging through the lumen of the needle to form a vacuum within the hermetically sealed packaging, and (e) measuring mass flow rate from the evacuated hermetically sealed packaging. Sensing of a mass flow rate from the evacuated hermetically sealed packaging above a threshold value indicates a leak in the hermetically sealed packaging.

LEGAL BASIS

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation; either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, NOT in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). *See,* M.P.E.P. § 2143.

As to the first criteria, it is necessary to ascertain whether or not the reference motivates one of ordinary skill in the relevant art, having the reference before him, to make the proposed substitution, combination, or modification. In re Linter, 458 F.2d 1013, 173 U.S.P.Q. 560, 562 (CCPA 1972). Obviousness can only be established where there is some teaching, suggestion or motivation in the prior art or in the knowledge generally available to one of ordinary skill in the art, to combine the references and produce the claimed invention. In re Fine, 837 F.2d 1071, 5 U.S.P.Q. 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *See,* M.P.E.P. § 2143.01. "[A]nalysis [of whether the subject matter of a claim is obvious] need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR Int'l v. Teleflex, Inc., 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385, 1396 (2007) quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336-37 (Fed. Cir. 2006); *see also* DyStar Textilfarben GmBH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1361, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006)("The motivation need not be found in the

references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself."); In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969)("Having established that this knowledge was in the art, the examiner could then properly rely, as put forth by the solicitor, on a conclusion of obviousness `from common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference.'); In re Hoeschele, 406 F.2d 1403, 1406-07, 160 USPQ 809, 811-812 (CCPA 1969) (" [I]t is proper to take into account not only specific teachings of the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom..."). The analysis supporting obviousness, however, should be made explicit and should "identify a reason that would have prompted a person of ordinary skill in the art to combine the elements" in the manner claimed. KSR, 127 S.Ct. at 1731, 81 USPQ2d at 1389.

NEITHER MAYER NOR GÜRICH ET AL.
DISCLOSE PULLING A VACUUM
OR THEREAFTER MEASURING MASS FLOW RATE

The Third and Fourth Aspects of the Present Claimed invention include the steps of evacuating gaseous content from within a hermetically sealed package to form a vacuum within the package, followed by measuring mass flow rate pulled from the evacuated package. The mass flow rate measured after the package has been evacuated is representative of the extent to which the package leaks as any mass flow detected after the package has been evacuated must predominantly be coming from leaks in the package.

Mayer does not disclose, teach or suggest evacuating the gaseous content of a package to form a vacuum. Indeed, Mayer actually teaches away from pulling such a vacuum as the instrument of Mayer is designed to measure the concentration of oxygen within the package and pulling a vacuum during the testing process would increase the risk of contaminating a gas sample pulled from the package with environmental air pulled into the package through any leaks in the package. See. M.P.E.P. § 2141.03 VI [PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS].

Gürich et al. does not disclose, teach or suggest evacuating the gaseous content of the cylinder, NOR measuring mass flow rate pulled from the evacuated cylinder. In fact, Gürich et al. does just the opposite and introduces pressurized gas into the cylinder at a known and measured constant rate.

NEITHER MAYER NOR GÜRICH ET AL.
PROVIDE ANY MOTIVE OR INCENTIVE TO ADD A MASS FLOW RATE SENSOR
TO THE INSTRUMENT DISCLOSED IN MAYER

The First and Second Aspects of the Invention are directed to an instrument for detecting leaks in hermetically sealed packaging. The instrument includes a needle having a lumen, a mass flow rate sensor, and a vacuum pump configured and arranged so as to be effective for evacuating gas from a hermetically sealed package through the lumen in the needle and directing mass flow from the evacuated package into operable contact with the mass flow rate sensor.

Mayer discloses an instrument and method for measuring the concentration of oxygen in a hermetically sealed package by pulling a gas sample from a hermetically sealed package and analyzing that sample with an oxygen sensor. The instrument and method disclosed in Mayer does NOT include a mass flow rate sensor for measuring the mass flow rate of gas pulled from the package. This is not surprising as such information is entirely irrelevant to a determination of oxygen concentration.

The instrument disclosed in Gürich et al. optionally uses a mass flow rate sensor for measuring the amount of a pressurizing gas introduced into a cylinder of an internal combustion engine. Data obtained from the mass flow rate sensor is used to calculate a leakage characteristic Q(p) for the cylinder based upon a change in pressure observed within the cylinder at different known mass flow rates.

Both the Mayer and Gürich et al. references are devoid of any disclosure, teaching, suggestion or motivation - express, implied or attainable through the application of common sense - to selectively incorporate the optional mass flow rate sensor from the instrument of Gürich et al. into the instrument of Mayer. Indeed, the arbitrary nature of such a combination is evident from the fact that incorporation of a mass flow rate sensor into the instrument of Mayer simply provides that instrument with the ability to measure the amount of gas removed from a package by the instrument during a testing cycle – a value having no meaning or significance to the instruments intended purpose of measuring the concentration of oxygen in a hermetically sealed package. It is only through the inappropriate use of Applicant's own disclosure as a blueprint for assembling otherwise disparate components from unrelated arts (*i.e.*, measuring the concentration of oxygen in a hermetically sealed package v. measuring the compression volume in a cylinder of an internal combustion engine) that the Examiner is able to recreate the Present Claimed Invention from Mayer and Gürich et al.

Withdrawal of this rejection is respectfully requested.

CONCLUSION

Applicant respectfully submits that all pending claims (claims 1-4) are in condition for allowance.

Respectfully submitted,

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By _____

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